FOR ARGUMENT

IN THE
Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-605

UNITED STATES OF AMERICA, et al.,
Petitioners,

v.

GLEN L. RUTHERFORD, et al.,
Respondents.

Brief Amicus Curiae of The McNaughton Foundation of California on Behalf of Robert Stickle, Steve Gadler, Dorothy Schires and Mrs. Doris Keith Representing a Class of Cancer Patients

STEPHEN TORNAY
Attorney at Law
1831 Fourth Avenue
San Diego, California 92101
Telephone: (714) 232-7171

Attorney for Amicus Curiae

INTERIM PRINTING & MAILING COMPANY
1105 WEST MORENA BOULEVARD, SAN DIEGO, CALIFORNIA 92110 — 275-3050

TABLE OF CONTENTS

TABLE OF AUTHORITIES CITED

TABLE OF AUTHORITIES CITED (Continued)

TABLE OF AUTHORITIES CITED (Continued)

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-605

UNITED STATES OF AMERICA, et al.,
Petitioners,

v.

GLEN L. RUTHERFORD, et al.,
Respondents.

Brief of Amicus Curiae of The McNaughton Foundation of California on Behalf of Robert Stickle, Steve Gadler, Dorothy Schires and Mrs. Doris Keith Representing a Class of Cancer Patients

INTEREST OF AMICUS CURIAE

Pursuant to Supreme Court Rule 42(1), this Amicus Curiae brief is submitted on behalf of the class of persons described as American cancer patients who have gone to the Republic of Mexico to receive treatment for cancer including the use of laetrile. These patients number in the thousands. One clinic, Centro Medico Delmar, Tiguana, Mexico, has served in excess

of 15,500 patients since 1974 and currently is receiving patients from the United States at the rate of approximately 3,700 new patients annually. Clinica Cydel, Tijuana, Mexico, has served approximately 3,500 patients since opening its doors and is receiving patients from the United States at the approximate rate of 850 new patients annually.

The staff of these facilities reveal that approximately eighty percent (80%) of the United States patients have come to these clinics after having been advised that their condition is terminal, conventional medicine can give them no further help; they seek treatment with laetrile as a last resort.

Treatment in Mexico by the clinics consists of a special diet, vitamins, minerals and enzymes; adequate rest and exercise; injectable and *oral* laetrile. Radiation therapy, conventional chemotherapy and surgery are used by these clinics at the discretion of the clinic's medical director.

The average stay in Mexico is approximately three weeks. Some patients stay at motels near the border in San Ysidro, California, and travel each day to the clinics approximately ten to fifteen miles away. Some patients stay at motels in Tijuana or in small bungalows provided by the clinics at a moderate rate of $14.00 per day for double occupancy. After approximately three weeks, the patient's initial course of treatment has been completed and many of the patients have improved to the point where they are ready to continue their treatment at home in the United States. The patient is supplied with a quantity of laetrile, both injectable and oral, as is determined by his attending physician. This initial supply is brought into the United States by the patient upon

presentation of the physician's affidavit and payment of applicable customs duties.

The vast majority of these returning patients desire to continue treatment with laetrile at their homes in the United States. It is at this point that the class of patients in whose interest this brief is being submitted emerges. Under the current affidavit system in use they are permitted to obtain additional supplies upon presentation of the physician's affidavit and the appointment of a properly designated agent for the importation of laetrile. It is this class of patients that will require appropriate relief from this Honorable Court in order to continue their treatment. The vast majority of these patients experience varying degrees of relief and benefits. These patients are generally free from pain without the use of narcotics; the quality of their lives is improved and the length extended.

SUMMARY OF ARGUMENT

Amicus concurs in the decision of the Tenth Circuit Court of Appeals but requests that this Court should expand the relief granted to the class of patients to include laetrile for oral administration. Whether on the grounds of a determination that the terms "safety" and "effectiveness" have no meaning to the terminally ill cancer patient or on the grounds of right of privacy. Access to laetrile, both intravenous and oral, should not be denied these patients until the clinical trials to be conducted under the direction of the National Cancer Institute, Department of Health, Education and Welfare, have been completed. Amicus urges the continued use of the current affidavit system pending the outcome of these clinical trials.

QUESTIONS PRESENTED

I.

WHETHER THE SAFETY AND EFFECTIVENESS REQUIREMENTS OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT SHOULD BE APPLIED TO INJECTABLE LAETRILE INTENDED FOR USE BY TERMINALLY ILL CANCER PATIENTS WHEN PROCURED BY A CERTIFIED LICENSED MEDICAL PRACTITIONER.

II.

WHETHER THE JUDGMENT OF THE TENTH CIRCUIT COURT OF APPEALS CAN BE UPHELD BY THE HOLDING OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA THAT THE DENIAL OF THE USE BY A TERMINALLY ILL CANCER PATIENT OF LAETRILE UNDER THE SUPERVISION OF A PHYSICIAN INVADES THE PATIENT'S RIGHT OF PRIVACY.

ARGUMENT

I.

WHETHER THE SAFETY AND EFFECTIVENESS REQUIREMENTS OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT SHOULD BE APPLIED TO INJECTABLE LAETRILE INTENDED FOR USE BY TERMINALLY ILL CANCER PATIENTS WHEN PROCURED BY A CERTIFIED LICENSED MEDICAL PRACTITIONER.

The Federal Food, Drug and Cosmetic Act (Act) defines a new drug as a drug "not generally recognized by qualified experts as safe and effective for its intended use," 21 U.S.C. 321, p. 1.

The decision of the Tenth Circuit Court of Appeals, *Rutherford v. United States,* 582 F.2d 1234, held that "as a matter of law, that the safety and effectiveness requirements of the statute as now written have no application to terminally ill cancer patients who desire to take the drug 'laetrile' intravenously," ibid. at page 1237. The Court further limited the procurement of intravenous injections to persons who are certified by a medical practitioner to be terminally ill of cancer.

The Tenth Circuit, in effect, continued the relief granted the patients in the United States District Court on grounds other than that upon which such relief was based in the District Court. Unfortunately, the relief limited the acquisition of laetrile to injectable laetrile.[1/]

[1/] The term laetrile is being used in this brief to avoid any confusion that might come about by the use of the term amygdalin.

Footnote 1 continued on following page.

It is urged by Amicus that the Tenth Circuit was correct in holding that the Commissioner of Food and Drugs erroneously applied the Federal Food, Drug and Cosmetic Act to the distribution of intravenous laetrile to terminally ill cancer patients. It is strongly suggested that that portion of the decree which permits only intravenous injections of

---

Footnote 1 continued

More properly, the subject matter being dealt with before the Court is the substance amygdalin. Amygdalin is extracted from the kernels of various fruits, mostly of the prunus species. Amygdalin is extracted from peach, bitter almond, prune and apricot kernels. The most available is apricot kernels, thus, most of the amygdalin that is extracted is extracted from this source. The term laetrile was first "coined" by Dr. Ernst T. Krebs, Jr. and is now used interchangeably with the term amygdalin. There have been several judicial determinations that have equated laetrile and amygdalin. *United States v. Spectro Foods Corporation*, Civ. - 76-101 (District N.J. 1976) affirmed in part, reversed in part, 544 F.2d 1175 (3rd Cir. 1976); *United States v. General Research Laboratories*, 397 F.Supp. 197 (C.D. Cal. 1975); *Rutherford v. United States*, 399 F.Supp. 1208, 1211 (W.D. Okla. 1979), 424 F.Supp. 105-106 (W.D. Okla. 1977). Cyanogenetic glucocides appear in many foods eaten by man including cassava, sweet potato, yam, maize and millet, bamboo and sugar cane, peas and beans (especially lima beans), kernel of almond, lemon, lime, arple, par, cherry, apricot, prune, peach and plum, (*Toxic Constituents of Plant Food Stuffs*, C.H. 5, R.D. Montgomery, Academy Press, 1969). (Lest wrong impressions be created by the title of the book "Toxic Constituents of Plant Food Stuffs," it should be noted that upon reading the article by R. D. Montgomery, one would quickly conclude that virtually no danger exists from ingestion of these food stuffs when eaten in normal quantities.)

laetrile should be broadened to include laetrile for administration by oral route.[2/]

(1) The rationale and basis upon which food, drugs and cosmetics are regulated is to protect the unwary customers in vital matters of health. *U.S. v. 250 Jars, etc. of U.S. Fancy Pure Honey*, (D.C. Mich. 1963) 218 F.Supp. 208, affirmed 344 F.2d 288. The line of cases that characterize this as the

---

2/ The current practice by experienced laetrile physicians in Mexico is to commence the treatment of cancer patients with high intravenous doses of laetrile. When the patient's condition justifies it, the patient is switched to a mixture of injectable as well as oral laetrile. This is an integral part of the entire treatment given by these physicians with laetrile. Undoubtedly, the ruling of the Tenth Circuit expressed by inference a possible misunderstanding as to the toxicity of laetrile by oral administration. The same Court also apparently revealed its unfamiliarity with current clinical practice in the administration of laetrile. It should be observed at this point that the route of oral administration presents no danger to the cancer patient when under the guidance of a licensed physician. Laetrile like any other substance, can be ingested in toxic quantities but this is true of many over-the-counter drugs sold without prescription and also of prescription items. This is not a valid reason to withhold it when recommended by a physician. The fears expressed by the U.S. Government and some of the amicus briefs reveal a lack of understanding of the toxicity of laetrile. The American Cancer Society has estimated that as many at 70,000 cancer patients in the United States have received laetrile therapy. This would, by necessity, include oral administration. The report of two deaths which are in themselves suspect and inconclusive leaves much to be desired in supporting claims of the toxicity of laetrile. It is estimated that as many as 1200 deaths occur annually in the United States from ingestion of aspirin. (Center for Disease Control, Atlanta, Georgia.) Yet aspirin is freely available to anyone who wishes to purchase it.

rationale behind the act are numerous, repetitious and center around the attempt to protect the consumer. The requirement of both safety and effectiveness in new drugs as provided by the Act is commendable and should be interpreted and enforced in a rational manner so as to give effect to the underlying purpose. Perhaps it is unworthy to say, but a necessary observation to make, that the safety and effectiveness requirements of the Federal Food, Drug and Cosmetic Act as related to the treatment of cancer is and has been more a statement of wishful thinking than a reality.

Unfortunately, statistics bear out the fact that virtually all methods of treatment of cancerous conditions by accepted modalities are neither "safe" nor "effective."[3]/ & [4]/

(Footnotes 3 and 4 are quoted from Judge Bohanon's decision in *Rutherford v. United States*, 438 F.Supp. 1287.)

3/ ". . . the treatments that are available are very often disfiguring; they can be painful; they can be unpleasant; they can even be risky." Emil J. Freireich, Professor of Medicine at the University of Texas, School of Medicine, Houston.

4/ 1977 *Cancer Facts and Figures* by the American Cancer Society estimates that 1977 will have produced an estimated 690,000 new cancer cases; and that over 54 million Americans now living will eventually have cancer, whichis one out of every four Americans living. The pamphlet also states that over the years cancer will strike in approximately two of every three families, that in the 1970's there will be an estimated 3.5 million cancer deaths, 6.5 million new cancer cases, and more than 10 million people under medical care for cancer. Only about 1/3 of all people who get cancer this year will be alive five years after treatment, according to the publication.

It is therefore submitted that exceptions to the safety and effectiveness requirements of the Food and Drug Administration have been carved out when dealing with cancer since drugs that are neither safe nor effective have been approved.

Safety is described in the brief by the United States by way of footnote at page 31, footnote 18, "(A) a drug is safe when the expected therapeutic gain justifies the risk entailed in using it . . .", Dr. Theodore G. Klumpp, Chief Drug Division, F.D.A. June 23, 1941.

Therefore, it appears that safety as a term is used in the relative context in relation to the risk involved. Effectiveness relates only to general recognition among "experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for such use . . .", 21 U.S.C. 321 p. 1.

The foregoing provides little guidance and in the light of the current methods of treatment for cancer, afford little assurance to the cancer patient.

The Tenth Circuit Court of Appeals was able to perceive this within the narrow limitation set forth by that Court. The decision is limited to terminally ill cancer patients and is further limited to intravenous injections of laetrile procured by a licensed practitioner. The Court cited no authority fo rits decision. Perhaps no such authority exists. However, this Honorable Court has never been bound by authority nor shackled by precedent. In enacting a statutory scheme of regulation such as the Federal Food, Drug and Cosmetic Act, Congress can never be expected to spell out conditions for all

circumstances that may arise in the complex nature of our societies. It is for the judiciary, therefore, to sometimes interpret a statute amidst the realities of life and to base its decision on grounds of reason and principle apart from authority.

The Tenth Circuit Court of Appeals in its decision revealed a depth of understanding of the terminally ill cancer patient's problems. The decision should be upheld but it is again suggested that the Court expand the relief granted to include access to laetrile in the oral administration form.

(2) The brief filed by the United States and that of two amicus briefs (Commonwealth of Massachusetts, State of California) have in greater or lesser degrees claimed inherent dangers from the use of laetrile due to its toxicity and further due to its ineffectiveness. Neither isue is properly before the Court but if unanswered, wrong impressions could be created. Therefore, a few comments should be made relative to these two subject matters.

Initially, it should be observed that as of this date (March, 1979) eighteen states in the United States have legalized the sale, and/or manufacture, of laetrile within those states.[5/]

5/ The following states have already legalized laetrile: Arizona, Alaska, Washington, Oregon, Idaho, Nevada, North Dakota, South Dakota, Kansas, Oklahoma, Texas, Louisiana, Florida, Illinois, Indiana, Maryland, New Hampshire, and New Jersey. (Bills have passed in one house of the State Legislature of the states of Michigan and Montana.) It is anticipated with reasonable certainty that a majority of the states will have legalized laetrile within the next year or two.

Amicus will ask the Court to take judicial notice that the legislative bodies of each of the several states have hearings and testimony offered, both pro and con, when considering a bill involving a substance that has apparently been as controversial as laetrile. Amicus will further request the Court to take judicial notice that each of these States, in the exercise of it(s) respective police powers, is primarily concerned with the safety, health and welfare of its citizens. Accordingly, based on this rather overwhelming indication of confidence as expressed by the legislative bodies of the states footnoted below, it becomes apparent that the toxicity claims are appreciably dissipated and the claims of ineffectiveness are similarly suspect. It is not the purpose or the function of this brief to delve into the effectiveness or into the safety of laetrile although on each of these factors, the Court would undoubtedly find some input useful.

The Court should be informed that currently the prestigious Mayo Clinic in Rochester, Minnesota, 55901, is designing a common protocol for the five institutions which have been selected by the National Cancer Institute, Department of Health, Education and Welfare, to carry out the forthcoming clinical trials of laetrile. In a copy of the proposed clinical trial obtained through the Freedom of Information Act, the following statement by Dr. Charles G. Moertel, M.D., of the Mayo Clinic appears as an introductory to the protocol for the clinical trials.[6/]

6/ A *Clinical Trial of Laetrile (Amygdalin) in the Treatment of Advanced Cancer*

I. Introduction

Laetrile (Amygdalin, Vitamin B-17) is one of the many natural cyanogenic glycosides. This substance was perhaps first isolated by

Footnote 6 continued on following page.

Thus, finally, adequate clinical trials are about to be commenced in which the question of efficacy will soon be

---

Footnote 6 continued

German chemists in 1832 and it was listed in the Merck Index in the late 19th century with no defined therapeutic indication.

Current use of Laetrile, dating from the early 1950's, can be ascribed to Dr. Ernest T. Krebs Jr. who theorized 1) Laetrile is metabolized by mammalian cells with the release of cyanide, 2) Detoxification of cyanide by the normal cell occurs promptly, converting free cyanide to thiocyanate, 3) An enzyme inhibition in the cancer cell prevents this detoxification and the free cyanide is therefore allowed to be specifically toxic to the cancer cell.

Animal tumor model studies of Laetrile have been generally stated to show no antineoplastic activity. Initial studies conducted at Memorial-Sloan Kettering by Kanematsu Sugiura, however, were reported as showing delayed appearance and growth of pulmonary metastasis in a spontaneous breast tumor system. He also claimed temporary retardation of growth of small primaries, inhibition of appearance of new tumors, and better health and appearance of treated mice. Later studies at the same institution conducted by Franz Schmidt gave results confirming the observations of Sugiura in one study out of three and this was only at borderline significance. The other two studies were negative. More recent investigations directed by Daniel S. Martin, C. Chester Stock, and Elizabeth Stockert have been uniformly negative. Some of these latter investigations have been blinded and conducted with direct participation by Doctor Sugiura. A large group of animal studies were also conducted at the Southern Research Institute and were stated to be negative, although analyses of these results by some have raised the question of antitumor activity in one of three dosage levels tested. Published negative evaluations in animal model systems also include those of Hill et al (Cancer Res. 36:2102) and Wadinsky (Cancer Chemother Rep 59:939). It must be concluded that in animal tumor studies, the effect of Laetrile has probably been negligible.

Toxicity of Laetrile in dosages currently employed for human cancer is assumed to be minimal, although toxic reactions have never been systematically observed and recorded. Apparently the

Footnote 6 continued on following page.

answered; the question of efficacy belongs in the clinics not in the courts.

Footnote 6 continued

only observed side effect is transient hypotension immediately following injection, and this is exceedingly rare. Nausea and vomiting have occurred infrequently after oral ingestion and these symptoms are said to subside with continued use. Animal toxicology studies of parenterally administered drug indicate that the dosages currently employed clinically are far below those at which significant toxic reactions would be anticipated. Toxicology of the orally administered drug, however, reveals that there are species to species differences. Though the dose tolerated in dogs is well above that planned in this study the defined Lethal Dose in the monkey and the rat is in the order of 2 grams/m^2. This is in contrast to the large clinical experience in humans where larger than proposed doses are prescribed and administered with little to no reported toxicity.

In the past, consideration of a clinical trial for Laetrile has been rejected by the medical and scientific community on the basis of inadequate preclinical evidence of antineoplastic activity. The usual criteria for according a new drug high priority for clinical trial, as established by both the National Cancer Institute and the Food and Drug Administration, have included at least a reasonable demonstration of antineoplastic activity in animal tumors. Although complete reliance on rodent tumor experience for admission of drugs to human clinical trial can be scientifically questioned, such a general policy seems reasonable in view of the lack of promising alternative screening procedures for therapeutic activity. A case for waving this precedent could only be made under exceptional circumstances, but such circumstances do now seem to exist for Laetrile. Today in the United States, Laetrile has become one of the most commonly employed chemotherapeutic agents for the treatment of cancer. It has been estimated that during 1977 some 2000 American practitioners were involved in administering over 1,000,000 grams of Laetrile per month to over 50,000 patients. From the standpoint of magnitude of use alone, Laetrile has become a public health issue of major significance.

Footnote 6 continued on following page.

Amicus, representing the class as set forth at the beginning of this brief, would like to briefly touch upon the method by

---

Footnote 6 continued

Most important with regard to the Laetrile question are the serious social, economic, political, and legal issues which have surrounded it. Organized medicine, the American Cancer Society, the National Cancer Institute, and the Food and Drug Administration, have previously taken strong stands against the use of Laetrile, but this stance has not seemed to be acceptable to the general public. Organized medicine has been depicted as depriving the dying cancer patient of a harmless treatment that could conceivably provide palliation, and, even if therapeutically inactive, could provide a psychologically beneficial placebo effect. Laetrile has become one of the most popular subject on the news media with heavy coverage in newspapers, magazines, radio, and television. Prominent United States Senators and Congressmen have called publically for a re-evaluation of the Laetrile question and the Senate Subcommittee on Health has held public hearing regarding Laetrile. On the state level, Laetrile has been legalized for either human use of manufacture or both in 17 of the 50 states. Any contention that these actions simply represented a response to a vocal minority would seem to be contradicted by a Harris poll in which a nationwide sampling favored legalization of Laetrile by a strong 53 to 23 percent majority. Laetrile has been, or is being, considered in 16 cases before Federal Courts. In those cases which have been decided, the decisions have overwhelmingly favored Laetrile. Use of Laetrile by the terminal cancer patient has been made legal through Federal District Court decision and this decision has been upheld by the Federal Court of Appeals. This issue is now pending before the United States Supreme Court. Laetrile is now allowed for treatment of any cancer patient, requiring only a short form be filled out which states little more than the patient has cancer and desire such treatment.

Certainly it may be argued that there is a segment of the American public that will pursue quack treatment regardless of what evidence is presented to them. The Laetrile issue, however, has clearly gone far beyond the point of just another quack medicine. Sound, sensible Americans are obviously confused and they are not convinced by the

Footnote 6 continued on following page.

which continued use of laetrile can be experienced by the terminally ill cancer patients pending the outcome of the clinical trials about to be commenced.

Certain references have been made to the "affidavit system." Briefly, this is a system worked out following the orders of the United States District Court for the Western District of Oklahoma following the decision of that Court in *Rutherford v. United States*, 499 F.Supp. 1208. In practice, the system is one in which duly licensed physicians or court approved foreign physicians, may sign affidavits. Cancer patients then, with this affidavit in hand, can obtain their supplies of laetrile as prescribed by their doctor.

Footnote 6 continued

arguments of Laetrile opponents or by the fact that Laetrile has no activity in experimental animals. Their concern has been overtly expressed by their elected representatives and by their Federal Courts. The welfare of this large segment of the American public cannot be dismissed with the argument that a handful of Laetrile zealots will never be convinced regardless of evidence.

If Laetrile is indeed worthless and a cruel hoax for the cancer victim, then the thinking, sensible American citizen should be presented with convincing evidence that will serve to protect him against such exploitation. If, on the other hand, the widespread public acceptance of Laetrile is indicative of some useful palliative effect, it is even more important that this effect be demonstrated in a convincing manner.

Considering the scope and impact of the Laetrile issue today, there would seem to be no reasonable alternative to a therapeutic trial conducted with objective methodology by experienced clinical cancer research groups whose results will be credible in the eyes of the medical community, the communications media, and the American public.

Amicus strenuously urges the Court that this system (affidavit) should be continued pending the outcome of the clinical tests on laetrile. The thousands of patients that Amicus represents should not be made exiles from their own country in order to continue their treatment. By granting the relief requested, pending completion of the clinical trials of laetrile by the National Cancer Institute, no conceivable harm could be caused to the government's position whereas irreparable harm could be sustained by the thousands of patients Amicus represents should the relief requested be denied and the clinical trials demonstrates the efficacy of laetrile.

II.

WHETHER THE JUDGMENT OF THE TENTH CIRCUIT COURT OF APPEALS CAN BE UPHELD BY THE HOLDING OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA THAT THE DENIAL OF THE USE BY A TERMINALLY ILL CANCER PATIENT OF LAETRILE UNDER THE SUPERVISION OF A PHYSICIAN INVADES THE PATIENT'S RIGHT OF PRIVACY.

The government argues in its brief that a terminally ill cancer patient enjoys no constitutional right of privacy which would protect him against an intrusion by the United States Government that would deny him access to the drug laetrile.

Three postulates are urged by the government. The first suggests that (1) laetrile is toxic, the second (2) denies the constitutional right of the patient to take a particular drug or

class of drugs for medical purposes and the third (3) alleges that even if such a constitutional right of privacy exists, such right to use laetrile is outweighed by compelling government interest in protecting the public health. Amicus contends that the United States is wrong on all three postulates.

A. The government first urges that laetrile is toxic. It is interesting to note that the District Court in which nontoxicity was found is the Court in which the evidence was reviewed. Questions of toxicity raised the spectre of possible deaths and the Court was thus entrusted with the sacred task of ruling on a possible death-dealing substance. The U.S. District Court for the Western District of Oklahoma, *Rutherford v. United States*, 438 F.Supp. 1287, found adequate proof by people who had actually used laetrile, as opposed to those who had not, that laetrile indeed was not toxic. The question of toxicity, properly speaking, is not really before this Court. The attempt at this late date to make it an issue before the Court is beyond the scope of this appeal. However, it would be appropriate to repeat that virtually every drug in use today is toxic when ingested or administered by other methods in excessive amounts. When laetrile is prescribed by an attending physician, it is perfectly safe. It should also be noted that a finding by the Commissioner that a drug is not recognized as safe by qualified experts is not a determination of toxicity. The range of safety does not limit itself to toxicity but it involves safety in varying degrees. In any event, when prescribed by a licensed medical practitioner, clearly there is no danger or the spectre of any harm to any person.

B. Next, the government claims that there is no constitutional right of privacy to use unproven or ineffective

drugs. This untenable argument fails to consider the fact that there are no safe drugs or treatments and there are no effective drugs or treatments for the care, treatment or prevention of cancer. Cast in this light, denial of even an unproven or ineffective drug that gives the terminally ill cancer patient hope and is taken by him under the guidance of a physician invades the right of privacy as described by Justice Brandeis in *Olmstead v. United States*, 227 U.S. 438, 478:

> "[T]he makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone - - the most comprehensive of rights and the right most valued by civilized men. To protect, that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation. . . ."

The cancer patient is left upon the horns of a dilemma; he is offered either unsafe and ineffective remedies sanctioned by the Federal Government or a nontoxic naturally occurring substance which has been present in the diet of man since before the dawn of history. Faced with these alternatives, the terminally ill cancer patient has, and understandably, frequently selected laetrile as his method of treatment. Little has

been said about the improved quality of life that is achieved by the patient receiving laetrile. Appetite is restored, weight increases, pain reduces and the patient experiences an increased sense of well-being. These are the findings of the *California Laetrile Report* of 1953. Within the framework of this circumstance the cancer patients represented by Amicus assert a right of privacy to make this "important decision." To deny him this right is truly an invasion of an area of privacy that has been long recognized by this Court in case after case. This Court has recognized that the right of privacy exists in many areas of our lives. Abortion, *Roe v. Wade*, 410 U.S. 113 (1973), *Doe v. Bolton*, 410 U.S. 179 (1973); marriage, *Loving v. Virginia*, 388 U.S. 1 (1967); procreation, *Skinner v. Oklahoma*, 316 U.S. 535 (1942); contraception, *Eisenstadt v. Baird*, 405 U.S. (1972); family relationships, *Prince v. Massachusetts*, 321 U.S. 158 (1944); child rearing and education, *Pierce v. Society of Sisters*, 268 U.S. 510 (1925). This Court has described the breadth of the right as ". . . independence in making certain kinds of important decisions." *Roe v. Whalen*, 429 U.S. at 599-600. Important decisions are not limited to those areas in which this Court has formerly found this fundamental right to exist.

The Government argues at page 60 of its brief, "the right claimed here of caring for one's health by obtaining a particular drug without government hindrance does not fall into any of those categories." A failure to fall "into any of those categories" (former decisions) does not mean that the right does not exist in other categories. In all probability, it is partly for this reason that this case is before this Court.

This is a case of first impression before this Court. There can be little doubt that this decision, one of life and death, is the type of "important decision" that this Court has recognized in determining the parameters of the right of privacy.

Recently the Supreme Court of the State of California, Sup. Ct. No. CR-32978, ___ Cal.3d ___ (1979), had an opportunity to rule on the constitutionality of a State Statute (Health and Safety Code 1707.1) which provides for criminal sanctions to any person, including a physician, who sells, delivers, prescribes or administers any drug or device used in the diagnosis, treatment, alleviation or cure of cancer which has not been approved by the federal agency (21 U.S.C. Section 355) or by the State Board (Cancer Advisory Council) (Health and Safety Code Section 1704).

Defendants, convicted under this statute, claimed a right of privacy in the patient to receive laetrile, the physician defendant claimed a derivative right from his patients. The convictions had been reversed by the District Court of Appeals in California, *People of the State of California v. Privitera, et al.*, 141 Cal.Rptr. 764, in a decision written by Judge Robert O. Staniforth holding that both the doctors' as well as the patients' right of privacy had been invaded. This searching opinion became the opinion of the dissent and was reprinted in the California Supreme Court. The logical arguments of Judge Staniforth are barely resistable. However, the Supreme Court held that the section under scrutiny (1707.1 of the Health and Safety Code of the State of California) did bear a reasonable relationship to the achievement of a legitimate state interest in the health and safety of its citizens.

It should be carefully pointed out, however, that this decision is very narrow in its terms dealing strictly with the constitutionality of the statute in the case under consideration by that Court. A quotation from this case (with apologies for lack of the page number) states as follows:

> "Defendants can take no comfort in the Court of Appeals decision for unlike *Rutherford* (referring to 582 Fed. 2d, 1234), this case is not an action on behalf of the class of terminally ill cancer patients. Whatever may be said in favor of permitting terminal cancer patients access to laetrile, there is no indication in the records that defendants sought to restrict their activities to that class when prescribing, distributing and administering laetrile. Indeed, the record reflects that Dr. Privitera sometimes neither took a medical history from, nor personally examined the patients for whom he prescribed laetrile. The lay defendants, of course, were not qualified to diagnose cancer, much less to determine whether a cancerous condition was 'terminal.' " (Emphasis by Court)

Thus it would appear that the California Supreme Court did recognize that terminally ill cancer patients fall within a totally different class; as to them, the right of privacy might easily have been found to exist for this class by the same Court. Certainly this is a reasonable inference.

C. The third argument of the government on the right of privacy contends that application of the safety and efficacy requirement of the Food, Drug and Cosmetic Act to laetrile is a reasonable means of serving a compelling government

interest in protecting the public health. Amicus agrees that the "safe" and "effective" requirements of the Food, Drug and Cosmetic Act are reasonable means of serving a compelling government interest in protecting health. There is no quarrel here. However, this broad statement is not reasonably related to the application of laetrile for reasons previously stated. In Sands, *Statutes and Statutory Construction* (4th ed. 1973), Section 58.04, the following statement appears:

> "Because of the deeply entrenched commitment of western society and law to the values of individualism, there is a pervasive preference for interpretations of doubtful statutes which favor individual rights. Thus statutes which impinge on fundamental freedoms are strictly construed." *Dombrowski v. Pfister,* 380 U.S. 479 (1965).

Also, from *Holy Trinity Church v. United States,* 143 U.S. 457 at 459 (1891):

> "It is a familiar rule, that a thing may be within the letter of the statute and yet not within the statute, because not within its spirit, nor within the intention of its makers . . . This is not the substitution of the will of the judge for that of the legislator, for frequently words of general meaning are used in a statute, words broad enough to include an act in question, and yet a consideration of the whole legislation, or of the circumstances surrounding its enactment, or of the absurd results which follow from giving such broad meaning to the words, makes it unreasonable to believe that the legislator intended to include the particular act."

It must be remembered that the specific subject matter before this Court is laetrile in its application only to terminally ill cancer patients under the supervision of a licensed physician. The Tenth Circuit Court's decision based upon reason and principle held that "safe and effective" requirements have no meaning to terminally ill cancer patients. Whether the restriction on government regulation of laetrile is thus obtained on a rule of statutory construction or on the constitutional grounds of right of privacy makes little difference to the suffering cancer patient who is told he is about to die. The relief requested is what is needed.

Cancer patients should not be made "exiles" from their own country, they should not be required to go to foreign jurisdictions in order to obtain the laetrile treatment which is a treatment of their own choice.

Finally, it is worthy to comment and speculate that the Tenth Circuit Court sensed the constitutional underpinnings in its decision but indulged in a rule of statutory construction to avoid the constitutional issue which is now before this Court. It is urged that a right of privacy exists in a terminally ill cancer patient to seek and obtain laetrile under the guidance of his physician for his personal use without unwarranted interference by the government.

CONCLUSION

For the reasons set forth in this brief it is respectfully urged that the Tenth Circuit Court decision should be affirmed, the relief expanded to include oral laetrile. Amicus recommends that the affidavit system now in use should be continued including oral laetrile pending the completion of the clinical trials under the direction of the National Cancer Institute, Department of Health, Education and Welfare.

Respectfully submitted,

STEPHEN TORNAY

Attorney for Amicus Curiae